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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,174	10/13/2006	Bruno Pasquale Franco Nardo	01213/0203491-US0	1175
7278	7590	07/24/2009	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			HAYMAN, IMANI N	
			ART UNIT	PAPER NUMBER
			3767	
			MAIL DATE	DELIVERY MODE
			07/24/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,174

**Applicant(s)**

NARDO ET AL.

**Examiner**

IMANI HAYMAN

**Art Unit**

3767

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 13, and 15-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

In response to the Amendment filed 20 April 2009, claims 11, 13, and 15-17 are pending.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11, 13, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weitzel et al. (US Patent No. 6,913,588 B2), hereinafter Weitzel in view of Davidner et al. (US 2002/0077581), hereinafter Davidner.

Regarding claim 11, Weitzel discloses the invention substantially as claimed for a machine suitable for regeneration of a human liver; comprising at least two catheters; an extracorporeal circuit configured to connect first and second catheters of the at least two catheters (figure 1). However, Weitzel is silent on an oxygenation device. Davidner discloses two catheters (151, 107) an extracorporeal circuit configured to connect first and second catheters of the at least two catheters (figure 1) with at least an oxygenation device (104) connected to said extracorporeal circuit, said oxygenation device being suitable to introduce oxygen into blood in extracorporeal circulation in said circuit [0014]; a control device configured to provide feedback control so as to regulate a quantity of oxygen provided to the oxygenation device; and the control device further configured to measure hematocrit and a partial pressure of molecular oxygen in the blood in extracorporeal circulation (figure1) [0046-0048, 0057, 0082, and 0086]. Hence, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Weitzel with the oxygenator device to gradually increase the oxygen content of the retroperfusate supplied to the patient [0042] and the microprocessor to receive and transmit operational information [0048] as taught by Davidner.

Regarding claim 13, Weitzel discloses the machine wherein there are also means for hemofiltration of the blood in extracorporeal circulation (figure 4, ref no. 300).

Regarding claim 15, Weitzel discloses the machine wherein there are also means designed to heat the blood in extracorporeal circulation (column 2, lines 30-31).

Regarding claim 16, Weitzel discloses the machine wherein there are also means designed to introduce anticoagulating substances into the blood in extracorporeal circulation (column 2, lines 31-33).

Regarding claim 17, Weitzel discloses the machine wherein there are also means to detect and eliminate any air bubbles present in the blood in extracorporeal circulation (figure 4, ref no. 182).

#### ***Response to Arguments***

5. Applicant's arguments with respect to claims 11, 13, and 15-17 have been considered but are moot in view of the new ground(s) of rejection. Regarding the amended independent claim (11), Davidner discloses a control device configured to provide feedback control so as to regulate a quantity of oxygen provided to the oxygenation device; and the control device further configured to measure hematocrit and a partial pressure of molecular oxygen in the blood in extracorporeal circulation [0046-0048, 0057, 0082, and 0086].

#### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IMANI HAYMAN whose telephone number is (571)270-5528. The examiner can normally be reached on MONDAY THRU FRIDAY 7:30 AM TO 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, KEVIN SIRMONS can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/I. H./  
Examiner, Art Unit 3767

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761